

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Assessment the effect of intraumbilical vein Oxytocin injection in comparison to normal saline on third stage of labor

#### Protocol summary

##### Summary

This study is aimed to compare the effect of intraumbilical vein oxytocin and normal saline on the third stage of labor. Pregnant women are randomly allocated into two groups of oxytocin and normal saline. In overall, 75 patients are participated in the study. It is a double-blind study (obstetricians and patients). Inclusion criteria: cephalic presentation and patients with first pregnancy. Exclusion criteria: multi gravity; severe anemia; uterine scar. In both groups, umbilical cord at a distance of one centimeter from the introitus is clamped immediately after the expulsion of the fetus. In the first group, 20 ml of normal saline is injected into the umbilical vein using syringe, and to prevent leakage of injected fluid, cord is re-clamped from above the space of injection site. In the second group, according to the same protocol, 30 units of oxytocin solved in 17 ml of normal saline (total 20 ml), is injected by needle into the umbilical vein. Time between intravenous injection of umbilical cord and placenta is measured by using of stopwatch. In the present study, hemoglobin and hematocrit level are also measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017052810340N15**

Registration date: **2017-06-29, 1396/04/08**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-06-29, 1396/04/08

##### Registrant information

Name

Mohammad Aryaie

##### Name of organization / entity

Golestan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 911 277 1798

##### Email address

aryaie@goums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Golestan University of Medical Science

##### Expected recruitment start date

2017-04-21, 1396/02/01

##### Expected recruitment end date

2017-07-21, 1396/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment the effect of intraumbilical vein Oxytocin injection in comparison to normal saline on third stage of labor

##### Public title

The effect of Oxytocin on the duration of third stage of labor

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: First pregnancy; singleton pregnancy; gestational age term (over 37 weeks); signs of labor (regular contractions with the appropriate power 3 per 10 minutes); cephalic presentation. Exclusion criteria were considered as: Multi gravity; polyhydramnios; severe

anemia; uterine scar; the use of forceps or vacuum; placenta previa; prolonged labor (over 20 hours); bleeding before delivery.

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 70

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

Patients would be allocated in to 2 groups using block allocation (block size 6) method.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethic Committee of Golestan University of Medical Science

**Street address**

4 Kilometer of Gorgan-sari Road, Falsafi educational campus, Vice Chancellor of Technology and Information, Gorgan

**City**

Gorgan

**Postal code****Approval date**

2017-05-16, 1396/02/26

**Ethics committee reference number**

IR.GOUMS.REC.1396.24

**Health conditions studied****1****Description of health condition studied**

duration of labor

**ICD-10 code**

O00-O99

**ICD-10 code description**

Pregnancy, childbirth and the puerperium

**Primary outcomes****1****Description**

Duration of third stage of labor

**Timepoint**

After intervention

**Method of measurement**

Stopwatch

**Secondary outcomes****1****Description**

Hemoglobin

**Timepoint**

After intervention

**Method of measurement**

Blood sample

**2****Description**

Hematocrit

**Timepoint**

After intervention

**Method of measurement**

Blood sample

**Intervention groups****1****Description**

Control group will receive 20ml of normal saline by injection into the intraumbilical vein.

**Category**

Placebo

**2****Description**

Intervention group will receive 30 units of oxytocin, dissolved in 17 ml of normal saline, by injection into the intraumbilical vein

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Sayyad Shirazi Hospital

**Full name of responsible person**

Ghazaleh Sadeghian

**Street address**

Shahid Sayyad Shirazi Hospital, Shahid Sayyad Shirazi Street, Gorgan City, Golestan Province

**City**  
Gorgan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Golestan University of Medical Sciences

**Full name of responsible person**

Mohsen Saeedi

**Street address**

4 Kilometer of Gorgansari Road, Falsafi educational campus, Vice Chancellor of Technology and Information, Gorgan

**City**

Gorgan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Golestan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Golestan University of Medical Science

**Full name of responsible person**

Ghazale Sadeghian

**Position**

Obstetricians

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Mohamma Aryaie

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MSc in Epidemiology

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*